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WESTERN DISTRICT OF LOUISIANA
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE)
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:
*Allen, et. al. v. Takeda Pharmaceuticals
North America, Inc., et al.*
(Case No. 12-cv-00064)

MAGISTRATE JUDGE HANNA

MEMORANDUM RULING:
EXPERT TESTIMONY CONCERNING "OUTCOME SCENARIO II"

This multidistrict litigation arises from product liability claims against the manufacturer and marketer of Actos® and other drugs containing pioglitazone. Pending before this Court is the Defendants' Motion to Exclude Testimony of Plaintiffs' Experts David Altman, M.D., Dan Bagwell, R.N., and Kristin Kucsma, M.A., Regarding "Outcome Scenario II,"¹ in which the Defendants seek to exclude testimony concerning the anticipated costs (and present value of those costs) should Mr. Allen's bladder cancer recur in a more dangerous form. For the reasons that follow, the Defendants' motion will be GRANTED on the evidence presented.

TESTIMONY UNDER CHALLENGE

The Plaintiffs will present evidence at trial that Mr. Allen has been diagnosed with, and has been treated for, bladder cancer. They also intend to present evidence that Mr. Allen's bladder cancer is expected to recur in the future. According to the Plaintiffs' experts, there are three possible future scenarios with regard to Mr. Allen's bladder cancer:

- Mr. Allen's cancer does not recur;

¹ Rec. Doc. 3469. This motion has been urged on behalf of all named defendants in this matter.

- Mr. Allen's cancer recurs in the same form that he previously experienced it (*i.e.*, non-muscle-invasive); or
- Mr. Allen's cancer recurs within five (5) years after his initial diagnosis of bladder cancer at the age of 56, and that such cancer is muscle-invasive.²

The latter possibility is known as "Outcome Scenario II."

With regard to Outcome Scenario II, the Plaintiffs intend to present to the jury evidence of the medical and other costs that can be expected to result. Specifically, the Plaintiffs intend to submit two sets of expert opinions:

- Either David Altman, M.D. or Dan Bagwell, R.N., is expected to present opinion testimony concerning Mr. Allen's future medical and life care needs, together with the costs that Mr. Allen can be expected to incur as a result of those needs;³ and
- Kristin Kucsma, M.A., an expert in the analysis of economic loss, cost of future health care and services, and other elements of economic damage, is expected to opine as to the present value of the future care costs identified by Dr. Altman or Nurse Bagwell.

The Defendants have declared that they do not intend, in the motion at bar, to challenge the anticipated testimony related to Outcome Scenarios I and III, but seek merely to have excluded the foregoing evidence associated with Outcome Scenario II.

APPLICABLE LAW

The opinion testimony under challenge must comply with the requirements of Rule 702 of the Federal Rules of Evidence in order to be admissible.

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

² See Plaintiffs' Opposition to Defendants' Motion to Exclude Testimony of Plaintiffs' Experts David Altman, M.D., Dan Bagwell, R.N., and Kristin Kucsma, M.A. Regarding "Outcome Scenario II," ["Opposition," Rec. Doc. 3613], at 9.

³ It is this Court's understanding that either Dr. Altman or Nurse Bagwell will testify on this point, and not both of them.

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.⁴

Federal jurisprudence clearly establishes that this Court has a gatekeeping role with regard to expert opinion testimony, requiring that such evidence meet the requirements of both reliability and relevance.⁵ The Defendants' Motion does not challenge the reliability of the challenged testimony, but addresses only its admissibility under the latter prong of the *Daubert* test. Specifically, the Defendants seek to have the evidence excluded as irrelevant for failing to reach the level of probability required by the Federal Rules of Evidence and substantive New York law.

Under the Federal Rules of Evidence, evidence is relevant if it has any tendency to make a fact more or less probable than it would be without the evidence, and the fact being proven or disproven is of consequence in determining the action.⁶ Relevant evidence is admissible; irrelevant evidence not admissible.⁷ Both the Plaintiffs and the Defendants agree that New York substantive law requires a plaintiff seeking to recover future medical expenses (as well as those expenses associated with such alleged future illness) to prove, to a reasonable medical certainty, that such future expenses will be incurred.⁸ The *Ivory* Court provided a persuasive explanation of the

⁴ F.R.E. 702.

⁵ See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993); *Moore v. Ashland Chemical, Inc.*, 151 F.3d 269, 275 (5th Cir. 1998) (*en banc*).

⁶ F.R.E. 401.

⁷ F.R.E. 402.

⁸ See *Marcoux v. Farm Service and Supplies, Inc.*, 290 F.Supp.2d 457, 479 (N.D.N.Y. 2003), citing *Patterson v. Kummer Development Corp.*, 302 A.D.2d 873, 875, 755 N.Y.S.2d 180, 182 [4th Dep't 2003]; *Swearingen v. Long*, 889 F.Supp. 587, 590 (N.D.N.Y. 1995); *Ivory v. International Business Machines Corp.*, 37 Misc. 3d 1221(A), 964

rationale for this requirement:

The Fourth Department [in *Askey v. Occidental Chem. Corp.*, 102 A.D.2d 130, 477 N.Y.S.2d 242 (4th Dept. 1984)] stated that, if a plaintiff seeks future medical expenses as an element of consequential damages, he must establish with a degree of reasonable medical certainty through expert testimony that such expenses will be incurred.⁹

* * *

Obviously, the reasonable certainty of the expenses themselves must flow from the reasonable certainty of the disease in the first instance. Otherwise, in this Court's view, to simply ignore a plaintiff's chances of actually becoming sick would make medical monitoring damages available for the asking and akin to a fear of disease claim without the attendant safeguards of genuineness and certainty required in said claims.¹⁰

Thus, under the Federal Rules of Evidence and applicable New York, substantive jurisprudence, the Plaintiffs (who seek to admit the evidence under challenge) bear the burden of proving its admissibility, *i.e.*, that it tends to make a relevant fact more likely than not and because the evidence at issue concerns future medical expenses, under New York substantive law, the Plaintiffs must prove their future damages to a reasonable medical certainty.

ANALYSIS

The Fifth Circuit has, on at least two separate occasions, recognized that District Courts sitting in diversity, apply state substantive law on the threshold question of the standard of proof required to recover future damages by an injured party.

In *Gideon v. Johns-Manville Sales Corp.*, 761 F.2d 1129, 1137 (5th Cir. 1985) the Fifth Circuit found authority under Texas law in upholding the district court's decision not to charge the jury that Gideon could not recover for fear of future injury and death where Texas law permitted

N.Y.S.2d 59, Case No. 2012-0768, 2012 N.Y.Misc. LEXIS 5226, at *4 (Sup. Ct. Bloom County, Nov. 15, 2012).

⁹ *Ivory*, 2012 N.Y.Misc. LEXIS 5226, at *9-10 (internal citations and quotation marks omitted).

¹⁰ *Id.* at *11 (citation omitted).

such recovery, and Texas's standard for such recovery was met.

In *Rodriguez v. Larson*, 259 Fed.Appx. 607, 609-610 (5th Cir. 2007) the Fifth Circuit, under a *de novo* review of a district court's denial of a motion for judgment as a matter of law, applied Texas's substantive law (the "reasonable probability rule") in determining whether the plaintiff had met the requisite burden, under Texas's law, to sustain an award for future damages.

Therefore, this Court will accept that a District Court, when determining the threshold question of the applicable standard of proof required for a finding of future damages, should look to the applicable state substantive law, if any, which in this case is New York Law. When looking to New York law, a U.S. District Court sitting in New York, in *Swearingen v. Long*, 889 F.Supp 587 @ 590 (N.D.N.Y. 1995) cited *Askey v. Occidental Chem. Corp.*, 102 A.D.2d 130, 136, 477 N.Y.S.2d 242, 247 (4th Dep't 1984), and stated:

The *Askey* court "held that plaintiffs who have been exposed to toxic substances had a claim for injuries not yet present, but restricted the rule to cases where the 'probability of their occurrence [amounted to] a reasonable certainty.' " *Penny v. United Fruit Co.*, 869 F.Supp. 122, 127 (E.D.N.Y.1994) (quoting *Askey*, 477 N.Y.S.2d at 247)). More particularly, the court explicitly stated that "[d]amages for the prospective consequences of a tortious injury are recoverable **only** if the prospective consequences may with **reasonable probability** be expected to flow from the past harm." *Askey*, 477 N.Y.S.2d at 247 (emphasis added). Thus, "[i]f a plaintiff seeks future medical expenses as an element of consequential damage, he must establish **with a degree of reasonable medical certainty** through expert testimony that such expenses will be incurred." *Id.* (citation omitted).

The U.S. District Court continued . . .

In a later case Judge Freeman recognized that " **'to meet this reasonably certain standard, courts have generally required plaintiffs to prove that it is more likely than not (a greater than 50% chance) that the expected consequences will occur.'** " *Penny*, 869 F.Supp. at 127 (quoting *Fusaro v. Porter-Hayden Co.*, 145 Misc.2d 911, 548 N.Y.S.2d 856, 859 (Sup.Ct.N.Y. County 1989) (quoting in turn *Wilson v. Johns-Manville Sales Corp.*, 684 F.2d 111, 119 (D.C.Cir.1982))).

Swearingen v. Long, 889 F. Supp. 587, 590 (N.D.N.Y. 1995)(emphasis added).¹¹

Under the substantive standard of proof embraced by the New York Courts, the evidence produced by the Plaintiffs does not, at this juncture, satisfy the burden required under New York law as to the “Outcome Scenario II.” Plaintiffs have produced evidence that Mr. Allen has a very high risk of recurrence of the *same type* of bladder cancer he experienced earlier-with ranges between 43% to 73%;¹² further, Plaintiffs have presented evidence that Mr. Allen’s risk of experiencing the specific type of cancer at issue in “Outcome Scenario II”—*i.e.*, muscle invasive bladder cancer— falls within the ranges of 8% and 35%.¹³ Additionally, the Plaintiffs have presented evidence that, in the opinions of several physicians, Mr. Allen is at *a very high risk for recurrence of his cancer*, that his morbidity will be worse if his bladder recurs than if the cancer had metastasized during its earlier appearance, and that Mr. Allen’s earlier tumor more probably than not invaded the *lamina propria*, creating a “greater risk” of muscle invasion in the event of a recurrence of bladder cancer.¹⁴ However, Plaintiffs do not provide evidence showing that “Outcome Scenario II” *i.e.*, that this muscle-invasive cancer is to a reasonable medical certainty, required under New York law, likely to occur *within 5 years, i.e.* falls within the approximate suggested by New York jurisprudence 50% range. Therefore, when judged against New York substantive law, the evidence presented does not support the level of risk argued for “Outcome Scenario II” embraced by New York substantive law.

This Court notes, however, it need not rely only on the noted substantive analysis. This Court, also, finds, pursuant to F.R.E. 104-403, plaintiffs have failed to meet their burden as to defendants’ evidence and argument to allow the challenged testimony. The Plaintiffs carry the

¹¹ This Court notes the *Swearingen* court references toxic tort exposure and as such is not factually identical, however, the same rationale should apply.

¹² Opposition, at 7.

¹³ Opposition, at 8.

¹⁴ Opposition, at 10-11.

threshold burden to present sufficient evidence to support their claims, consequently, movants can carry their burden on motion by showing an absence of evidence as to any challenged issue and plaintiffs must thereafter respond with evidence. Here, a substantive issue is presented folded within a *Daubert* challenge to an expert's testimony. Defendants argue plaintiffs cannot and have not presented sufficient evidence to meet the requisite substantive standard and thus, the expert should not be allowed to testify as to possible future damages, i.e. costs for a condition for which there is not sufficient evidence under New York substantive law. Based upon submissions received to date, this Court agrees. However, on a F.R.E. 104-403 analysis, this Court notes, neither the experts who quantified the risk of a muscle-invasive bladder cancer, nor those experts who merely described that risk—included any indication that Mr. Allen will, to any acceptable degree of medical certainty, develop muscle-invasive bladder cancer within the next five years. Consequently, based upon the testimony presented, this Court would find on a F.R.E. 104-403 analysis the evidence of costs/damages for muscle-invasive bladder cancer to be too speculative, and whatever probative value it might have to be is substantially outweighed by unfair prejudice, confusion of the issues, and the potential to mislead the jury.

CONCLUSION

For the foregoing reasons, the Defendants' Motion to Exclude Testimony of Plaintiffs' Experts David Altman, M.D., Dan Bagwell, R.N., and Kristin Kucsma, M.A. Regarding "Outcome Scenario II" will be GRANTED on the evidence presented. Of course, should, at trial, the Plaintiffs present evidence demonstrating that Mr. Allen will face, to a reasonable medical certainty, the risk of muscle-invasive bladder cancer within the next five (5) years, Counsel are invited request reconsideration of the instant decision. In the event of such a request, however, Counsel are instructed to raise the issue outside of the presence of the jury, and are admonished not to attempt

to present evidence concerning Outcome Scenario II until and unless express leave of Court has been granted.

THUS DONE AND SIGNED this 3 day of December, 2013.



REBECCA F. DOHERTY
UNITED STATES DISTRICT JUDGE